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Technology
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June 25, 2008

US EPA Office of Pollution Prevention and Toxics
EPA East Building Room 6428
Attn: Section 8(e)
1201 Constitution Avenue, NW
Washington, DC 20004

SUBJECT: TSCA 8(e) Notice

Dear TSCA Section 8(e) Coordinator:

On behalf of Akzo Nobel Polymer Chemicals, LLC, we are submitting results of an OECD 422 study conducted with 2,2-Bis(t-butylperoxy isopropyl)benzene (CAS #25155-25-3).

The test article was administered, in corn oil, once daily by gavage to male rats for at least 44 days and to female rats for 14 days during the pre-pairing period, pairing, gestation and lactation periods until day 4 post partum at 0 (vehicle control), 100, 300 or 1000 mg/kg/day..

There was a decrease in body weight during the study and decreased food consumption during pre-pairing in the 1000 mg/kg/day group.

Three of ten dams in the 1000 mg/kg/day dose group were not pregnant. The fertility index was 70% in this group compared to 100% in the control and remaining treated groups. The number of corpora lutea, the implantation rate and the number of living pups at first litter check were slightly reduced and postnatal loss was increased.

Liver weights in males and females in all treated groups were statistically significantly increased and mean kidney weights were statistically significantly increased in the 1000 mg/kg/day group. Organ to body weight ratio was significantly increased for the liver in all treated groups and in the 300 and 1000 mg/kg/day groups and for kidneys in these two groups. These effects were considered due to an increased metabolism and excretion of the test article.

Liver centrilobular hepatocellular hypertrophy and diffuse hepatocellular hypertrophy were reported in males and females which increased in incidence and severity with increasing dose. These were considered adaptive changes and not considered an adverse effect.

Minimally to moderately increased incidence and minimally to slightly increased severity of diffuse follicular cell hypertrophy of the thyroid gland were noted in males and females of the 1000 mg/kg/day group. This increase was considered a likely consequent to an enhanced liver cell metabolism due to the hepatocellular hypertrophy and not to represent a direct effect of the test article.

The kidneys in all males exhibited slight to moderate diffuse tubular degeneration/regeneration in the 1000 mg/kg/day. Minimal to slight multifocal tubular degeneration/regeneration was noted in some males in the 300 mg/kg/day group and in some females the 1000 mg/kg/day group, associated with minimal to slight tubular casts in two of the females. There was a slight increased incidence of focal tubular degeneration/regeneration in females in the 1000 mg/kg/day group and a slightly increased incidence and severity of hyaline droplets in the proximal convoluted tubules in males in the 300 and 1000 mg/kg/day group.

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Histopatholgy, performed on the reproductive organs of the 1000 mg/kg/day dose group, did not reveal relevant changes when compared to control reproductive organs.

In the offspring, mean body weight of the pups per group was statistically significantly reduced on day 4 post partum in the 300 and 1000 mg/kg groups. Litter weight gain at day 4 post partum was reduced. No test item related findings were noted a necropsy of the offspring.

The NOAEL was considered to be 100 mg/kg/day for both parental animals and the offspring.

Please contact me at (312) 544-7061 if you have any questions regarding this letter.

Sincerely,

Louette Rausch, M.S.
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